



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/551,437

09/29/2005

Katsuya Togawa

MIY-0206

2960

74384

7590

10/03/2008

Cheng Law Group, PLLC  
1100 17th Street, N.W.  
Suite 503  
Washington, DC 20036

EXAMINER

GERIDO, DWAN A

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

10/03/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,437	<b>Applicant(s)</b> TOGAWA ET AL.	
	<b>Examiner</b> Dwan A. Gerido, Ph.D.	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9-29-2005</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

4. not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al., (US 3,837,376) in view of McEwen et al., (US 5,308,506).

Art Unit: 1797

6. With regards to claim 1, Brown et al., teach a method of filtering a sample comprising a sample collection part for storing a sample (figure 1 #10), a plug member (figure 1 #18), filter member (figure 1 #15), a sample storage part (figure 1 #15). Brown et al., also teach filtering the sample by a pressure difference between the sample collection and storage parts while the plug member is pierced by a needle (column 3 lines 31-45, figures 2 and 3). Brown et al., do not explicitly teach sample collection by a vacuum blood collection needle. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brown et al., wherein any manner of blood collection is utilized in order to collect a sufficient volume of blood. Brown et al do not teach a plug member hermetically sealing the opening.

McEwen et al., teach a method of separating a sample of blood wherein a plug member hermetically seals the sample container and the area around a piercing needle (column 9 lines 58-62). McEwen et al., also teach a vacuum to draw the sample liquid into the tube (column 9 lines 46-51). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brown et al., in view of McEwen et al., in order to draw a sample into a container, and to prevent contamination of the sample prior to testing.

7. With regards to claim 2, Brown et al., teach a hollow needle (column 3 lines 13, figure 1 #20).

8. Claims 3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al., (US 3,837,376) in view of McEwen et al., (US 5,308,506) as applied to claim 1 above, and further in view of Krug (US 2,833,281).

Art Unit: 1797

9. With regards to claims 3 and 6 Brown et al., in view of McEwen et al., do not teach a needle with a communication groove on its outer surface and extending from needlepoint to an opposite end.

Krug teaches a venting needle comprising a groove extending from the needle point to an opposite end of the needle. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brown et al., in view of McEwen et al., in further view of Krug in order to form an air channel between the interior and exterior of a receptacle as taught by Krug.

10. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al., (US 3,837,376) in view of Faulkner et al., (US 5,624,554).

11. With regards to claim 4, Brown et al., teach a jig for collecting a sample comprising a sample collection part for storing a sample (figure 1 #10), a plug member (figure 1 #18), filter member (figure 1 #15), a sample storage part (figure 1 #15). Brown et al., also teach filtering the sample by a pressure difference between the sample collection and storage parts while the plug member is pierced by a needle (column 3 lines 31-45, figures 2 and 3). Brown et al., also teach a gripping portion attached to the needle (figure 1 #21), a communication needle having a flow channel (figures 2 and 3 #20) and a skirt portion extending in the axial direction of the needle (figure 4 #19). Brown et al., do not teach a vane on the needle of the communication guide.

Faulkner et al., teach a collection device with a vane positioned at the base of the projection within the device (figure 1 #'s 21 and 22). It would have been obvious to one of

Art Unit: 1797

ordinary skill in the art to modify Brown et al., in view of Faulkner et al., in order to provide an agitation means inside the sample container as taught by Faulkner et al.

12. With regards to claim 5, Brown et al., teach a hollow needle (column 3 lines 13, figure 1 #20).

13. Claims 7-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al., (US 3,837,376) in view of Kasai et al., (US 5,213,765).

14. With regards to claim 7, Brown et al., teach a sample collecting container comprising a sample collection part for storing a sample (figure 1 #10), a plug member (figure 1 #18), filter member (figure 1 #15), a sample storage part (figure 1 #15). Brown et al., also teach filtering the sample by a pressure difference between the sample collection and storage parts while the plug member is pierced by a needle (column 3 lines 31-45, figures 2 and 3). In addition, Brown et al., teach the sample collection part, filter member, and sample storage part connected with each other, and the internal pressure of sample storage part being reduced (figures 2 and 3). Brown et al., does not teach the plug member being hermetically sealed by a removable sealing member on the outer surface of the plug.

Kasai et al., teach a blood collection tube comprising a hermetically sealed plug member and a sealing member on the outer surface of the plug member (column 2 lines 55-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brown et al., in view of Kasai et al., to provide a resalable sealing member in order to prevent contamination of samples in the container.

15. With regards to claims 8 and 9, Kasai et al., teach a sealing member as a sheet composed of rubber affixed to the outer surface of the plug member, and covering the outer surface where

Art Unit: 1797

the plug member is punctured, and the sealing member being a plug press (column 2 lines 55-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brown et al., in view of Kasai et al., to provide a resalable sealing member in order to prevent contamination of samples in the container.

16. With regards to claims 10 and 11, Brown et al., teach a sample collecting container comprising a sample collection part for storing a sample (figure 1 #10), a plug member (figure 1 #18), filter member (figure 1 #15), a sample storage part (figure 1 #15). Brown et al., also teach filtering the sample by a pressure difference between the sample collection and storage parts while the plug member is pierced by a needle (column 3 lines 31-45, figures 2 and 3). In addition, Brown et al., teach the sample collection part, filter member, and sample storage part connected with each other, and the internal pressure of sample storage part being reduced wherein, an open hole and flow channel are formed between the storage and filter members thereby connecting the through hole and the sample collection part (figures 2 and 3). Brown et al., does not teach the plug member being hermetically sealed by a removable sealing member on the outer surface of the plug.

Kasai et al., teach a blood collection tube comprising a hermetically sealed plug member and a sealing member on the outer surface of the plug member (column 2 lines 55-65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Brown et al., in view of Kasai et al., to provide a resalable sealing member in order to prevent contamination of samples in the container.

Art Unit: 1797

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwan A. Gerido, Ph.D. whose telephone number is (571)270-3714. The examiner can normally be reached on Monday - Friday, 9:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/  
Primary Examiner, Art Unit 1797  
DAG